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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,854	10/22/1998	STEFAN JOOS	3528.38.USOO	8548

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1655	23

DATE MAILED: 01/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)	
09/171,854	JOOS ET AL.	
Examiner	**Art Unit**	
Bradley L. Sisson	1655	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 January 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *09 November 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-7*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit: 1655

Continuation of 5. does NOT place the application in condition for allowance because: While the claims have been amended to reflect in the preamble and in the results step that the intent is to detect "chromosomal overrepresentations," the specification does not enable such a method as it relates to the defined method steps. The Office action of May 2001 sets forth at page 4 the enabling method found in the disclosure. The recited method found in amended claim 1 does not necessarily result in the intended end product. Careful review of the method of claim 1 finds that one is to start with, and ends with normal cells. Initially, one is to isolate the DNA from the normal cells, amplify it with tagged primers, then take that amplified-tagged DNA and use it in an in situ hybridization reaction where the target is a sample of study cells. Interestingly, the DNA of the sample cells, which seemingly has the tagged extended primers present as probes, if not the entire amplified genome of the "control cells," is then subjected to additional amplification with none other than the same set of primers used in the initial amplification step that was performed on the control/normal cells in step (a). Such an amplification step would seemingly result in the generation of more of the same amplified, and tagged sequences. This second amplification product is then used in a hybridization reaction with normal cells (step (d)). The method does not require any partitioning of the first and second amplification products, but seemingly does require the use of a combined first and second amplification product in the cohybridization step- step (d). Even when the cohybridization step is to be performed, the only thing that is being hybridized and detected is normal DNA. It is not abundantly clear how hybridization of a tagged probe set to normal DNA will result in the requisite detection of any change in copy number of any sequence when by default, the target is normal. As presently worded, it would appear that the method encompasses the amplification and quantification of polyA/T sequences that are found at the end of every mammalian gene. The specification has not set forth the parameters by which an increase or decrease of such a sequence could be readily determined. Applicant is urged to give careful consideration as to how the enabling method found in the disclosure can be represented in the claims such that the requisite end result can be realized.

In the even that an appeal brief is to be filed, claims 1-7 would be rejected under 35 USC 112, first paragraph, as not being enabling for the method as presently claimed.

Claims 1-5 and 8 would remain rejected under 35 USC 112, first paragraph, as not satisfying the written description requirement. While applicant has presented argument at page 5 of the response wherein attention is directed to the amendments made to the claims, it is noted, supra, that the specification does not enable the claimed method and as such, the specification does not provide an adequate written description of said claimed method so as to reasonably convey that applicant was in possession of same at the time of filing. With respect to the kit of claim 8, it is noted that here applicant is claiming a profoundly large genus of chemical complexes. The specification does not reasonably suggest that applicant was in possession of such an immense genus at the time of filing. While applicant may well argue that there is little difficulty is generating such a genus of compounds, and that the genus is ever expanding, such arguments are not persuasive toward the withdrawal of this aspect of the rejection as the ease or difficulty in arriving at the genus of products is not at issue. What is at issue is whether the specification, as filed, provides an adequate description of each of the members of the genus. The few species exemplified do not meet the test for an adequate number. In support of this position, attention is directed to the decision in In re Shokal, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

***

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but also to define what it is, the situation is otherwise.

Acknowledgement is made of the request for the withdrawal of the finality of the Office action of 09 May 2001. The argument that the introduction of new references to reject claim 8 somehow constitutes a new ground of rejection and that finality should be withdrawn has not been found to be persuasive. In support of this position, it is noted that claim 8 was amended by applicant's response received 25 September 2000. Accordingly, the Office is correct in raising new grounds of rejection in response to the amendment.

Applicant's argument at page 6 of the response that the rejection of claim 8 under 35 USC 103(a) is improper as the cited prior art does not teach detecting chromosomal overrepresentations is not persuasive towards the withdrawal of the rejection. It is noted with particularity that the claim is drawn to a kit, not a method. Accordingly, the intended use of the kit does not have to be taught in the prior art so long as the prior art reasonably suggests combining these same elements in a kit for any other purpose. As set forth at page 8 of the Final Office action, the prior art correctly suggests just such components or elements and the rejection correctly identifies why one of ordinary skill in the art would have been motivated to have compiled same. Accordingly, the rejection is proper and has been maintained.

Applicant's request for the withdrawal of finality is also not persuasive, as applicant has filed a Notice of Appeal. Given that applicant has the right to appeal any claim that ahs been either finally rejected, or has been rejected twice by the Office, the aspect of applicant having filed an appeal in the case further signifies that prosecution on the merits is appropriately closed. Accordingly, the request for the Office to reopen prosecution on the merits is DISMISSED.